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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/792,258

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Kenneth F. Buechler

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10/09/2007

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/792,258

Applicant(s)

BUECHLER, KENNETH F.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The arguments/remarks dated 17 July 2007 have been received. Claims 11-17 are pending.
2. All rejections not reiterated herein below are withdrawn in view of the arguments.

### *Priority*

3. This application discloses and claims subject matter disclosed in prior Application No. 07/887,526 filed 21 May 1993, and names an inventor or inventors named in the prior application. Accordingly, this application constitutes a continuation or division.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 11-14 and 16-17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilding et al (US 5,637,469).

Wilding is entitled to the earliest priority date of 01 May 1992 and discloses a mesoscale flow system comprising a housing having a sample flow channel, extending from the inlet port, and an analyte detection region in fluid communication with the flow channel. The analyte detection region is provided with a binding moiety such as an antibody, immobilized therewithin. See column 2, lines 61-67 and column 3, lines 43-65. Samples enter the flow system through an inlet port by capillary action. See column 3, lines 40-42. The device also comprises sensors that detect the agglutination or flow impedance upon analyte binding. The presence of a preselected analyte in a fluid sample may be detected by sensing analyte-induced changes in sample fluid flow properties, such as changes in the pressure or electrical conductivity. See column 4, lines 21-30. Wilding teaches that the device may include two or more separate flow systems fed by a common inlet port with different binding moieties to enable the detection of two more analytes simultaneously. See column 4, lines 45-50. Wilding also discloses that the device may be fabricated with multiple detector capabilities so as to expand capabilities for assay and process monitoring to virtually any system. See column 5, table 1. Wilding also teaches beads such as magnetic beads or polymeric

beads disposed in the binding regions and antibodies immobilized thereon. See column 9, lines 7-13 and lines 54-65.

Even though Wilding does not specifically state that the device comprising a labeled reagent dissolvably disposed on a surface within said housing, Wilding does teach that binding moieties such as enzyme-labeled binding partners may be immobilized in the device using techniques well-known in the art. See column 9, lines 24-34. Therefore, a skilled artisan would have had a reasonable expectation of success in placing a labeled reagent in the device of Wilding as taught to obtain the advantage of having a device that requires minimal input from a user.

#### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding in view of Wilding et al (US 5,726,026).

See the discussion of Wilding '469 above. This reference differs from the instant invention in failing to teach the use of amperometric measurement.

Wilding '026, however, teaches substantially the same device and further teaches that detection techniques used the device are those customarily used in binding assays including measuring electrochemical signals by amperometric and or potentiometric techniques.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Wilding '469 using the detection techniques taught by Wilding '026 because such techniques are well-known in the art and '469 specially teaches that the device may be fabricated with multiple detector capabilities so as to expand capabilities for assay and process monitoring to virtually any system.

### *Conclusion*

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641

9/28/07